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KENNEDY, ENZI RESPOND TO GAO DRUG SAFETY REPORT

Washington, DC—Today, the Government Accountability Office (GAO) released a report entitled “Drug Safety: Improvement Needed in FDA Post Market Decision-making and Oversight Process” that details shortcomings in the Food and Drug Administration’s post-market drug safety system. The GAO recommended that Congress should consider giving FDA the authority to require post-market drug safety studies.

Senator Mike Enzi, chairman of the Health, Education, Labor and Pensions Committee, and Senator Edward M. Kennedy, ranking member, are working on legislation that will address many of the shortcomings currently experienced with post-market drug safety.

Senator Kennedy said, “The new GAO report underscores the urgency of our efforts to enact comprehensive drug safety legislation. Americans expect their medicines to be safe, and we have an obligation to ensure that FDA regulation of drugs, at approval and after, remains the gold standard.”

Senator Enzi said, “This report is extremely helpful in evaluating the procedures used by the FDA to keep tabs on drugs once they are approved and allowed on the market. It is critical that we maintain public confidence in the FDA’s ability to protect the public health. Senator Kennedy and I are working across party lines to exercise careful and responsible oversight of the FDA, and we plan to introduce comprehensive drug safety legislation soon.”

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